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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,442	03/22/2001	Sean Ekins	PC10607AMEB	4594

7590

01/14/2004

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EXAMINER
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MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/814,442

Applicant(s)

EKINS ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-18 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

***Election/Restrictions***

Claim 19 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election of an enzyme was made **without** traverse in Paper No. 4, filed 4/7/03.

It is noted that receptors and transporters, recited in claim 20, are also nonelected species.

An action on the merits of claims 1-18 and 20, as they read on an enzyme, follows. All rejections and objections not reiterated below are hereby withdrawn.

***Information Disclosure Statement***

The information disclosure statement filed 7/11/03 has been considered in full.

The information disclosure statement filed 11/28/03 fails to comply with 37 CFR 1.97(c) because it lacks a statement as specified in 37 CFR 1.97(e) or a fee as set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered.

***Drawings***

The drawings were received on 10/28/03. These drawings are acceptable to the examiner.

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***Double Patenting***

Applicant is advised that should claims 11 and 12 be found allowable, claims 13 and 14, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 13 requires that steps (i)-(iv) be performed before steps (a) and (b). As steps (i)-(iv) of claim 13 are identical to steps (a)-(d) of claim 11, and steps (a) and (b) of claim 13 are identical to steps (e) and (f), claim 13 is duplicative of claim 11. Claims 12 and 14 are also duplicative as the parent claims are duplicative.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 15 recite the limitation "the preselected concentration X", each in steps (c). Claim 15 also recites the phrase in the preamble. There is insufficient antecedent basis for this limitation in the claims, therefore the claims are indefinite.

Claim 11, in step (a), claim 13 in step (i), and claim 15 in step (a) recite the phrase "different known concentrations". It is unclear what is at the "different known concentrations"; i.e. the target or compounds to be tested, therefore the claims are indefinite. Similarly, steps (b) and (ii) recite performing an assay at three or more concentrations, but it is unclear whether these are intended to be different concentrations of target, compound, or some combination thereof, therefore the claims are further indefinite.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over MOODY et al. (Xenobiotica (1/1999) vol. 29 (1), pp. 53-75) in view of LEHNINGER (Biochemistry, 2<sup>nd</sup> edition (1975) Worth Publishers, NY).

Claim 15 recites a method for facilitating IC<sub>50</sub> concentrations by developing or identifying an assay for measuring percent inhibition of a "target" at different concentrations (of a compound?), performing an assay using at least 11 compounds, at least one of which is a control, for at least 3 concentrations (interpreted by the examiner to be concentrations of the compounds), plotting dose-response curves for the compounds and deriving a mathematical relationship between IC<sub>50</sub> and corresponding percent inhibitions at a particular concentration. Claim 16 limits the dose response curve to the Hill function. Claim 17 limits the assay to be one for drug-drug interactions related to cytochromes. Claim 18 limits the enzyme to particular cytochromes. Claim 20 limits the "target" to an enzyme.

MOODY teaches a method of facilitating IC<sub>50</sub> determination for a variety of cytochromes, including CYP2C9, CYP2D6, CYP3A4, CYP1A2, and CYP2C19 wherein 10 compounds and a control are screened in a biological assay at seven different concentrations, and a dose response curve determined using the Hill function (p. 57). It is noted that the equation taught by MOODY on p. 57 is the same as that recited in instant claim 16, expressed in a different order. MOODY also teaches that IC<sub>50</sub> of test compounds may be determined using regression analysis of the dose-response curves (p. 58). MOODY does not teach the exact equation recited in claim 15.

LEHNINGER teaches that the concentration (of an inhibitor) and/or percent inhibition of any enzyme may be determined using the Lineweaver-Burke equation (pp. 195 and 198-199). It is noted that the equation of claim 15 is merely a simplified version of a Lineweaver-Burke equation, and that the "constants" are not defined or otherwise limited in the claims.

It would have been obvious to one of ordinary skill in the art to use the Lineweaver-Burke analysis or equation of LEHNINGER to facilitate determination of IC<sub>50</sub> of a compound based on dose-response curve in the method of MOODY where the motivation would have been to use a well-known regression analysis, as suggested by the regression analysis and equations of MOODY.

### ***Conclusion***

Claims 11-18 and 20 are rejected; claim 19 is withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

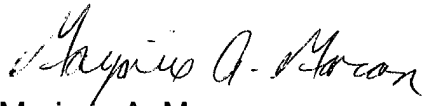
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0549.

  
Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

mam